IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of

GING et al. Atty. Ref.: 4398-286

Serial No. 10/781,949 TC/A.U.: 3772

Filed: February 20, 2004 Examiner: Nihir B.Patel

For: NASAL MASK ASSEMBLY

* *

September 30, 2008

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

Appellant hereby **appeals** to the Board of Patent Appeals and Interferences from the last decision of the Examiner.

TABLE OF CONTENTS

(I) REAL PARTY IN INTEREST

The real party in interest is ResMed Limited, a corporation of the country of Australia, by way of Assignments recorded at Reel/Frame 015561/0896 and 015561/0906.

(II) RELATED APPEALS AND INTERFERENCES

The appellant, the undersigned, and the assignee are not aware of any related appeals, interferences, or judicial proceedings (past or present), which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

(III) STATUS OF CLAIMS

The application was originally filed with claims 1-13. Claims 14-28 were added by subsequent Amendments. Claims 2, 3, 7, 13-19 and 25-28 have been cancelled without prejudice or disclaimer. Claims 1, 4-6, 8-12, and 20-24 are thus pending.

Claims 1 and 4-6 have been allowed.

Claims 8-12 and 20-24 have been rejected and are on appeal.

(IV) STATUS OF AMENDMENTS

An Amendment After Final Rejection was filed June 4, 2008. Claims 7, 19, and 25-27 were cancelled without prejudice or disclaimer and claims 8, 9, 20, and 22 were rewritten in independent form.

A June 30, 2008 Advisory Action indicated that the June 4, 2008 Amendment would not be entered for purposes of appeal.

Appellants filed a Notice of Appeal with Pre-Appeal Request for Review on July 7, 2008. In the Statement of Arguments, Appellants noted the refusal to enter the June 4, 2008 Amendment was improper under 37 C.F.R. §116(b)(2).

An August 14, 2008 Advisory Action indicated that the June 4, 2008 Amendment would be entered for purposes of appeal.

All amendments have been entered and are of record.

(V) SUMMARY OF CLAIMED SUBJECT MATTER

The references to the specification and drawings are illustrative and for explanatory purposes only, and not an admission that the claimed inventions are limited to any, or all, of the sample embodiments disclosed in the application.

8. A nasal mask (100) (Fig. 2) having a relatively rigid mask frame (120) and a relatively softer cushion (110) provided to said frame (120) (Figs. 12, 13, 15, page 12, [0085]), said cushion comprising:

an outer membrane (910) including a face-contact portion (1110) to form a seal with the patient (Fig. 13, page 13, [0088]);

a frame connection portion (1120) opposite the face-contact portion (1110) (Fig. 13, page 13, [0088]);

an inwardly sloping or stepped outer wall (1130) between the outer membrane (910) and the frame connection portion (1120) (Fig. 13, page 13, [0088]); and

an underlying rim (920) positioned below the membrane (910) (Fig. 12, page 12, [0085]),

wherein the membrane (910) and the rim (920) are formed and positioned with respect to one another to accommodate at least one of a pre-adult patient or a small sized adult patient (Page 13, [0087] and [0088]) and the cushion (110) includes a nasal bridge region (930), a top lip region (950) and two side regions (940) (Figs. 12-16, page 13, lines 1-2), and wherein a projected area of the frame connection portion (1120) is generally larger than an area defined by the face-contact portion (1110) of the membrane (910) (Fig. 13, [0088]), wherein:

the membrane (910) and rim (920) each have an orifice (975; 985) (Fig. 12, page 13, [0091]),

a width (Fig. 19) of said membrane orifice (975) is between about 30 and 32mm in said lip region (950), between about 18 and 20 mm in each said side region (940), and between about 22 and 24mm in said nasal bridge region (930) (page 15, [0094]),

a width (Fig. 18) of the rim orifice (985) is about 34 and 36mm in the nasal bridge region (930), between about 32 and 34mm in said lip region (950), and between about 42 and 44mm in each said side region (940) of the cushion (page 15, [0094]),

the membrane (910) and the rim (920) each have a height as measured from a portion of the cushion (110) that engages the frame (120),

the membrane height (Fig. 19) is about 27 and 35mm in the nasal bridge region (930), between about 19 and 22mm in the lip region (950), and between about 33-35mm in each said side region (940) (page 15, [0094]),

the rim height (Fig. 18) is between about 13 and 18mm in the nasal bridge region (930) and the lip region (950) (page 15, [0094]), and

the rim height (Fig. 18) in each said side portion (940) is between about 25 and 27mm (page 15, [0094]).

9. A nasal mask (100) (Fig. 2) having a relatively rigid mask frame (120) and a relatively softer cushion (110) provided to said frame (120) (Figs. 12, 13, 15, page 12, [0085]), said cushion comprising:

an outer membrane including a face-contact portion (1110) to form a seal with the patient (Fig. 13, page 13, [0088]);

a frame connection portion (1120) opposite the face-contact portion (1110) (Fig. 13, page 13, [0088]);

an inwardly sloping or stepped outer wall (1130) between the outer membrane (910) and the frame connection portion (1120) (Fig. 13, page 13, [0088]); and

an underlying rim (920) positioned below the membrane (910) (Fig. 12, page 12, [0085]),

wherein the membrane (910) and the rim (920) are formed and positioned with respect to one another to accommodate at least one of a pre-adult patient or a small sized adult patient (page 13, [0087] and [0088]) and the cushion (110) includes a nasal bridge region (930), a top lip region (950) and two side regions (940) (Figs. 12-16, page 13, lines 1-2), and wherein a projected area of the frame connection portion (1120) is generally larger than an area defined by the face-contact portion (1110) of the membrane (910) (page 13, [0088]), wherein the rim (920) includes an aperture (985) having a width of between about 30-42mm (Figs. 12 and 18 and 22, page 16, [0099]), an effective height as vertically measured from an edge of the rim (920) to a top of the cushion (110) as seen in plan view of between about 32-42mm (Fig. 22, page 16, [0099]), and an effective bridge depth of between about 13-24mm as vertically measured from the membrane in the nasal bridge region (930) to the rim (920) in each said side region in top view (Fig. 24, page 16, [0099]).

10. The nasal mask of claim 9, wherein the width is between about 39-40mm, the height is about 35mm and the depth is less than about 15mm (page 16, [0099]).

11. The nasal mask of claim 9, wherein the width is about 34-35mm, the height is about 40mm and the depth is about 20mm (page 16, [0099]).

12. The nasal mask of claim 9, wherein the membrane (910) generally follows a contour of the rim (920) (Fig. 12, page 12, [0085]).

20. A nasal mask (100) (Fig. 2) having a relatively rigid mask frame (120) and a relatively softer cushion (110) provided to said frame (120) (Figs. 12, 13, 15, page 12, [0085]), said cushion comprising:

an outer membrane (910) including a face-contact portion (1110) to form a seal with the patient (Fig. 13, page 13, [0088]);

a frame connection portion (1120) opposite the face-contact portion (1110) (Fig. 13, page 13, [0088]);

an inwardly sloping or stepped outer wall (1130) between the outer membrane (910) and the frame connection portion (1120) (Fig. 13, page 13, [0088]); and

an underlying rim (920) positioned below the membrane (910) (Fig. 12, page 12, [0085]),

wherein the membrane (910) and the rim (920) are formed and positioned with respect to one another to accommodate at least one of a pre-adult patient or a small sized adult patient (page 13, [0087] and [0088]) and the cushion (110) includes a nasal bridge region (930), a top lip region (950) and two side regions (940) (Figs. 12-16, page 13, lines 1-2), and wherein a projected area of the frame connection portion (1120) is generally larger than an area defined by the face-contact portion (1110) of the membrane

(910) (page 13, [0088]) wherein the membrane (910) and the rim (920) are formed and positioned with respect to one another to accommodate a pre-adult patient aged 16 years or less (page 13, [0087]), wherein:

the membrane (910) and rim (920) each have an orifice (975; 985) (Fig. 12, page 13, [0091]),

a width (Fig. 19) of said membrane orifice (975) is between about 30 and 32mm in said lip region (950), between about 18 and 20 mm in each said side region (940), and between about 22 and 24mm in said nasal bridge region (930) (page 15, [0094]), and

a width (Fig. 18) of the rim orifice (920) is about 34 and 36mm in the nasal bridge region (930), between about 32 and 34mm in said lip region (950), and between about 42 and 44mm in each said side region (940) of the cushion (110) (page 15, [0094]).

21. The nasal mask of claim 20, wherein the membrane (910) and the rim (920) each have a height as measured from a portion (1120) of the cushion (110) that engages the frame (120),

the membrane height is about 27 and 35mm in the nasal bridge region (930), between about 19 and 22mm in the lip region (950), and between about 33-35mm in each said side region (940),

the rim height is between about 13 and 18mm in the nasal bridge region (930) and the lip region (950), and

the rim height in each said side portion (940) is between about 25 and 27mm (page 15, [0094], lines 15-22).

22. A nasal mask (100) (Fig. 2) having a relatively rigid mask frame (120) and a relatively softer cushion (110) provided to said frame (120) (Figs. 12, 13, 15, page 12, [0085]), said cushion (110) comprising:

an outer membrane (910) including a face-contact portion (1110) to form a seal with the patient (Fig. 13, page 13, [0088]);

a frame connection portion (1120) opposite the face-contact portion (1110) (Fig. 13, page 13, [0088]);

an inwardly sloping or stepped outer wall (1130) between the outer membrane (910) and the frame connection portion (1120) (Fig. 13, page 13, [0088]); and

an underlying rim (920) positioned below the membrane (910) (Fig. 12, page 12, [0085]),

wherein the membrane (910) and the rim (920) are formed and positioned with respect to one another to accommodate at least one of a pre-adult patient or a small sized adult patient (page 13, [0087] and [0088]) and the cushion (110) includes a nasal bridge region (930), a top lip region (950) and two side regions (940) (Figs. 12-16, page 13, lines 1-2), and wherein a projected area of the frame connection portion (1120) is generally larger than an area defined by the face-contact portion (1110) of the membrane (910) (page 13, [0088]) wherein the membrane (910) and the rim (920) are formed and positioned with respect to one another to accommodate a pre-adult patient aged 16 years or less (page 13, [0087]), wherein the rim (920) includes an aperture (985) (Figs. 12 and 18) having a width of between about 30-42mm, an effective height (Fig. 22) as vertically measured from an edge of the rim (920) to a top of the cushion (110) as seen in plan view of between about 32-42mm, and an effective bridge depth (Fig. 24) of between about 13-

24mm as vertically measured from the membrane in the nasal bridge region (930) to the rim (920) in each said side region (940) in top view (page 16, [0099]).

23. The nasal mask of claim 22, wherein the width is between about 39-40mm, the height is about 35mm and the depth is less than about 15mm (page 16, [0099]).

24. The nasal mask of claim 23, wherein the width is about 34-35mm, the height is about 40mm and the depth is about 20mm (page 16, [0099]).

(VI) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 8-12 and 20-24 were rejected under 35 U.S.C. §103(a) over Palkon et al. (U.S. 7,007,696).

(VII) ARGUMENT

A. Claim 8 Is Not Obvious Over Palkon et al.

Claim 8 recites, *inter alia*, the membrane and rim each have an orifice. A width of the membrane orifice is between about 30 and 32mm in the lip region, between about 18 and 20 mm in each side region, and between about 22 and 24mm in the nasal bridge region. A width of the rim orifice is about 34 and 36mm in the nasal bridge region, between about 32 and 34mm in the lip region, and between about 42 and 44mm in each side region of the cushion.

The membrane and the rim each have a height as measured from a portion of the cushion that engages the frame. The membrane height is about 27 and 35mm in the nasal bridge region, between about 19 and 22mm in the lip region, and between about 33-35mm in each side region. The rim height is between about 13 and 18mm in the nasal bridge region and the lip region, and the rim height in each said side portion is between about 25 and 27mm.

The Office Action, on pages 4-5, paragraph number 12, acknowledges that Palkon et al. do not disclose or suggest any of the values of the features recited in claim 8. The Office Action concludes, however, that it would have been obvious to one of ordinary skill in the art to modify the mask cushion of Palkon et al. to include the exact dimensions recited in claim 8, "since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art." The Office Action then cites In re Aller, 220 F.2d 454, 105 USPQ 233 (CCPA 1955).

Appellants have repeatedly traversed the examiner's reliance on the rationale used by the court in In re Aller on the grounds that the facts of In re Aller are not sufficiently similar to the instant application to permit the examiner to rely on the rationale used by the Court in determining obviousness, particularly considering the examiner's reliance solely on the case for the determination of obviousness.

In response to Appellants' arguments, the examiner responded, in the June 30 and August 14, 2008 Advisory Actions, that "[t]he phrase optimum or workable ranges basically implies to any type of measurement units whether its temperature or a fitting measurement." Appellants respectfully disagree.

The facts of In re Aller are discussed in M.P.E.P. §2144.05(II).A. The case of In re Aller involved a claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70%. The claimed process was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%. In other words, the prior art at issue in In re Aller disclosed some value for temperature and acid concentration that differed from the claimed temperature and acid concentration.

In distinct contrast, Palkon et al. do not disclose or suggest any value for 1) the width of the membrane orifice, 2) the width of the rim orifice, 3) the membrane heights in each of the three regions, including the lip region, the nasal bridge region, and the side regions, and/or 4) the rim heights in each of the three regions, as recited in claim 8. Accordingly, the facts of In re Aller are not sufficiently similar to the instant application to permit the examiner to rely solely on the Court's rationale.

As Appellants have also repeatedly noted, M.P.E.P. §2144.05(II).B. discusses the case of In re Antoine, 559 F2d 618, 195 USPQ 6 (CCPA 1977). As the Court found in the case of In re Antoine, a particular parameter must be recognized by the prior art as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of the variable might be characterized as routine experimentation.

Palkon et al. do not disclose or suggest that any of the features (i.e. rim and membrane orifice width, membrane heights, and rim heights) in claim 8 are result-effective variables. Palkon et al. disclose in column 4, lines 6-26, that the use of three or more membranes is an improvement over the use of two membranes commonly used and seems to provide significant advances in comfort for the user. In the first embodiment of FIGS. 6 and 7, the thicknesses of the membranes 46, 47 and 48 change between the lip region 39 of the cushion 30 and the nasal bridge region 38 of the cushion 30. The membranes 46b, 47, and 48b at the nasal bridge region 38 of the cushion 30 are all about the same thickness and all, preferably are as thin as the membrane 48a at the lip region 39 of the cushion 30. At the lip region 39 the membranes have different thicknesses with, for instance membrane 46a being 0.06 inches thick, the membrane 47a being about 0.03 inches thick and membrane 48a being about 0.02 inches thick. The change in thickness of the membrane between the lip region 39 and the nasal bridge region 38 occurs in the cheek region 40. The advantages of the embodiment illustrated in FIGS. 6 and 7 as well as hereinafter is the use of the triple membrane system in combination with the varying thickness in the membrane in order to provide not only a soft feeling cushion but also an improved seal. (Underlining emphasis added.)

Palkon et al. further disclose in column 4, lines 44-47, that the variable thicknesses in the membranes 46, 47 and 48 are a significant feature of the invention and provide a significant improvement in the comfort of the cushion 30.

In the third embodiment shown in FIGS. 10A, 10B and 11, Palkon et al. disclose in column 5, lines 17-29, the other than straight portion 151 of the side wall 150 is a significant improvement in the present invention in that the portion 151 is more compressible and provides a far improved sealing mechanism to the nasal bridge region of the cushion 30A. The remaining portions of the cushion 30A other than the side wall portion 151 is the same as shown in the embodiments illustrated in FIGS. 6 and 7. However, preferably the side wall portion 45A in FIG. 6 is extended somewhat as shown in FIGS. 10A and 10B and 11 and provides an improved angle of contact when the cushion 30A is worn by a user; and in the preferred embodiment is 1.95 inches in the lip region and 2.15 inches in the nasal bridge region. (Underlining emphasis added.)

Palkon et al. also disclose in column 5, lines 45-48, that FIGS. 10A and 10B contains many actual measurements from one preferred embodiment of the present invention, but are included only for purposes of illustration and not by way of limitation. A review of the image file wrapper (IFW) of U.S. Patent 7,007,696 to Palkon et al. reveals that FIGS. 10A and 10B were in fact originally filed with dimensions. However, none of the dimensions correspond to the features of claim 8.

It is clear from the disclosure discussed above that the only result-effective variables recognized by Palkon et al. are the variable thicknesses of the membranes and the length of the sidewall portions of the cushion. Moreover, it is the combination of the varying thicknesses of the membranes in combination with the triple membrane system of

Palkon et al. that provides a soft feeling and improved sealing. Palkon et al. do not recognize that any of 1) a width of the membrane orifice, 2) a width of the rim orifice, 3) a membrane height, and/or 4) a rim height, in any of the nasal bridge, lip and/or side regions, is a result-effective variable. Accordingly, it would not have been obvious to one of ordinary skill in the art to modify Palkon et al. through routine experimentation or optimization to arrive at the dimensions of the features recited in claim 8.

Claim 8 also recites, *inter alia*, the membrane and the rim are formed and positioned with respect to one another to accommodate at least one of a pre-adult patient or a small sized adult patient.

As discussed in the previous responses, the treatment of Obstructive Sleep Apnea Syndrome (OSAS) in children represents different considerations than treatment in adults, in particular because of the differences in the shapes of infant and adult faces. See, for example, paragraphs [0007] – [0014] of the instant application. As recognized in the prior art, see for example [0014] of the instant application, the development of masks for non-adult patients generally involved a scaling down of adult masks. Although the prior art discussed in paragraph [0014] discusses some of the problems associated with the scaling down of adult masks, and presents its own solutions to the development of infant masks, none of the prior art of record suggests the features recited in claim 8. For example, the prior art discussed in paragraph [0014] of the instant application discloses a cushion comprising a membrane, but does not disclose or suggest an underlying rim positioned below the membrane, and having the features recited in claim 8.

The failure of the prior art to recognize any of the features recited in claim 8 clearly establishes non-obviousness.

B. Claims 9-12 Are Not Obvious Over Palkon et al.

Claim 9 recites, *inter alia*, the rim includes an aperture having a width of between about 30-42mm, an effective height as vertically measured from an edge of the rim to a top of the cushion as seen in plan view of between about 32-42mm, and an effective bridge depth of between about 13-24mm as vertically measured from the membrane in the nasal bridge region to the rim in each side region in top view.

Palkon et al. do not disclose or suggest that either 1) a rim orifice, 2) an effective height, and 3) an effective bridge depth is a result effective variable that may be modified or optimized to provide a recognized result. Palkon et al. only recognize the varying thickness of the triple membranes in the cheek region and the other than straight portion of the side wall of the cushion as features of their cushion which may be modified to improve the sealing function and/or comfort of the cushion. Accordingly, it would not have been obvious to modify, or optimize, the cushion of Palkon et al. to arrive at the invention of claim 9.

Claim 9 also recites, *inter alia*, the membrane and the rim are formed and positioned with respect to one another to accommodate at least one of a pre-adult patient or a small sized adult patient. Palkon et al. do not disclose or suggest that their triple membrane cushion is formed to accommodate a pre-adult or small sized adult patient. Therefore, it could not have been obvious to one of ordinary skill in the art, absent hindsight reasoning, to modify the cushion of Palkon et al. to include the features recited in claim 9.

Claims 10-12 recite additional features and are allowable for the same reasons as claim 9, and for the additional features recited therein.

C. Claims 20 and 21 Are Not Obvious Over Palkon et al.

Claim 20 recites, *inter alia*, the membrane and rim each have an orifice. A width of the membrane orifice is between about 30 and 32mm in the lip region, between about 18 and 20 mm in each side region, and between about 22 and 24mm in the nasal bridge region. A width of the rim orifice is about 34 and 36mm in the nasal bridge region, between about 32 and 34mm in the lip region, and between about 42 and 44mm in each side region of the cushion.

Palkon et al. do not disclose or suggest the features recited in claim 20, and thus, absent hindsight reasoning, it could not have been obvious to one of ordinary skill in the art to modify, or optimize, the cushion of Palkon et al. to include the recited features. Moreover, claim 20 also recites that the membrane and rim are formed and positioned with respect to one another to accommodate at least one of a pre-adult patient or a small sized adult patient. As Palkon et al., and the prior art of record, do not disclose or suggest such features, claim 20 is non-obvious.

Claim 21 recites additional features, including the membrane and the rim each having a height as measured from a portion of the cushion that engages the frame. The membrane height is about 27 and 35mm in the nasal bridge region, between about 19 and 22mm in the lip region, and between about 33-35mm in each side region.

The rim height is between about 13 and 18mm in the nasal bridge region and the lip region. The rim height in each side portion is between about 25 and 27mm.

The features recited in claim 21 are not recognized by Palkon et al., or any other prior art, as providing a result that can be improved or optimized. Therefore, claim 21 is not rendered obvious by Palkon et al. or any of the other prior art of record.

D. Claims 22-24 Are Not Obvious Over Palkon et al.

Claim 22 recites, *inter alia*, the rim includes an aperture having a width of between about 30-42mm, an effective height as vertically measured from an edge of the rim to a top of the cushion as seen in plan view of between about 32-42mm, and an effective bridge depth of between about 13-24mm as vertically measured from the membrane in the nasal bridge region to the rim in each said side region in top view.

Claim 22 further recites, *inter alia*, the membrane and the rim are formed and positioned with respect to one another to accommodate at least one of a pre-adult patient aged 16 years or less or a small sized adult patient.

Neither Palkon et al., nor any of the other prior art of record, disclose or suggest the features recited in claim 22, or disclose or suggest that such features can be modified, or optimized, to provide a recognized result. Accordingly, claim 22 is non-obviousness.

Claims 23 and 24 recite additional features that are not discloses or suggested by the prior art and are therefore non-obvious.

CONCLUSION

In conclusion it is believed that the application is in clear condition for allowance; therefore, early reversal of the Final Rejection and passage of the subject application to issue are earnestly solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /John P. Darling/
John P. Darling
Reg. No. 44,482

JPD:tlm
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100

(VIII) CLAIMS APPENDIX

8. A nasal mask having a relatively rigid mask frame and a relatively softer cushion provided to said frame, said cushion comprising:

an outer membrane including a face-contact portion to form a seal with the patient;

a frame connection portion opposite the face-contact portion;

an inwardly sloping or stepped outer wall between the outer membrane and the frame connection portion; and

an underlying rim positioned below the membrane,

wherein the membrane and the rim are formed and positioned with respect to one another to accommodate at least one of a pre-adult patient or a small sized adult patient and the cushion includes a nasal bridge region, a top lip region and two side regions, and wherein a projected area of the frame connection portion is generally larger than an area defined by the face-contact portion of the membrane, wherein:

the membrane and rim each have an orifice,

a width of said membrane orifice is between about 30 and 32mm in said lip region, between about 18 and 20 mm in each said side region, and between about 22 and 24mm in said nasal bridge region,

a width of the rim orifice is about 34 and 36mm in the nasal bridge region, between about 32 and 34mm in said lip region, and between about 42 and 44mm in each said side region of the cushion,

the membrane and the rim each have a height as measured from a portion of the cushion that engages the frame,

the membrane height is about 27 and 35mm in the nasal bridge region, between about 19 and 22mm in the lip region, and between about 33-35mm in each said side region,

the rim height is between about 13 and 18mm in the nasal bridge region and the lip region, and

the rim height in each said side portion is between about 25 and 27mm.

9. A nasal mask having a relatively rigid mask frame and a relatively softer cushion provided to said frame, said cushion comprising:

an outer membrane including a face-contact portion to form a seal with the patient;

a frame connection portion opposite the face-contact portion;

an inwardly sloping or stepped outer wall between the outer membrane and the frame connection portion; and

an underlying rim positioned below the membrane,

wherein the membrane and the rim are formed and positioned with respect to one another to accommodate at least one of a pre-adult patient or a small sized adult patient and the cushion includes a nasal bridge region, a top lip region and two side regions, and wherein a projected area of the frame connection portion is generally larger than an area defined by the face-contact portion of the membrane, wherein the rim includes an aperture having a width of between about 30-42mm, an effective height as vertically measured from an edge of the rim to a top of the cushion as seen in plan view of between about 32-42mm, and an effective bridge depth of between about 13-24mm as vertically

measured from the membrane in the nasal bridge region to the rim in each said side region in top view.

10. The nasal mask of claim 9, wherein the width is between about 39-40mm, the height is about 35mm and the depth is less than about 15mm.

11. The nasal mask of claim 9, wherein the width is about 34-35mm, the height is about 40mm and the depth is about 20mm.

12. The nasal mask of claim 9, wherein the membrane generally follows a contour of the rim.

20. A nasal mask having a relatively rigid mask frame and a relatively softer cushion provided to said frame, said cushion comprising:

an outer membrane including a face-contact portion to form a seal with the patient;

a frame connection portion opposite the face-contact portion;

an inwardly sloping or stepped outer wall between the outer membrane and the frame connection portion; and

an underlying rim positioned below the membrane,

wherein the membrane and the rim are formed and positioned with respect to one another to accommodate at least one of a pre-adult patient or a small sized adult patient and the cushion includes a nasal bridge region, a top lip region and two side regions, and wherein a projected area of the frame connection portion is generally larger than an area

defined by the face-contact portion of the membrane wherein the membrane and the rim are formed and positioned with respect to one another to accommodate a pre-adult patient aged 16 years or less, wherein:

the membrane and rim each have an orifice,

a width of said membrane orifice is between about 30 and 32mm in said lip region, between about 18 and 20 mm in each said side region, and between about 22 and 24mm in said nasal bridge region, and

a width of the rim orifice is about 34 and 36mm in the nasal bridge region, between about 32 and 34mm in said lip region, and between about 42 and 44mm in each said side region of the cushion.

21. The nasal mask of claim 20, wherein the membrane and the rim each have a height as measured from a portion of the cushion that engages the frame,

the membrane height is about 27 and 35mm in the nasal bridge region, between about 19 and 22mm in the lip region, and between about 33-35mm in each said side region,

the rim height is between about 13 and 18mm in the nasal bridge region and the lip region, and

the rim height in each said side portion is between about 25 and 27mm.

22. A nasal mask having a relatively rigid mask frame and a relatively softer cushion provided to said frame, said cushion comprising:

an outer membrane including a face-contact portion to form a seal with the patient;

a frame connection portion opposite the face-contact portion;

an inwardly sloping or stepped outer wall between the outer membrane and the frame connection portion; and

an underlying rim positioned below the membrane,

wherein the membrane and the rim are formed and positioned with respect to one another to accommodate at least one of a pre-adult patient or a small sized adult patient and the cushion includes a nasal bridge region, a top lip region and two side regions, and wherein a projected area of the frame connection portion is generally larger than an area defined by the face-contact portion of the membrane wherein the membrane and the rim are formed and positioned with respect to one another to accommodate a pre-adult patient aged 16 years or less, wherein the rim includes an aperture having a width of between about 30-42mm, an effective height as vertically measured from an edge of the rim to a top of the cushion as seen in plan view of between about 32-42mm, and an effective bridge depth of between about 13-24mm as vertically measured from the membrane in the nasal bridge region to the rim in each said side region in top view.

23. The nasal mask of claim 22, wherein the width is between about 39-40mm, the height is about 35mm and the depth is less than about 15mm.

24. The nasal mask of claim 23, wherein the width is about 34-35mm, the height is about 40mm and the depth is about 20mm.

(IX) EVIDENCE APPENDIX

None.

(X) RELATED PROCEEDINGS APPENDIX

None.